

**REMARKS**

Upon entry of this amendment, claims 1 and 3 will be amended and claim 2 will be canceled without prejudice or disclaimer of the subject matter recited therein so that claims 1 and 3-29 will remain pending.

By the amendment herein, claim 1 has been amended to include the subject matter of dependent claim 2, and claim 3 has been amended to depend upon claim 1 instead of canceled claim 2. Accordingly, this amendment is properly enterable after final rejection because the subject matter of claim 2 has previously been considered in combination with the subject matter of claim 1. Therefore, the amendment seeks to place the application in condition for allowance or a least reduce issues for appeal.

Reconsideration and allowance of the application are respectfully requested.

**Information Disclosure Statements**

Applicant is submitting herewith a Third Supplemental Information Disclosure Statement to update information relating to Application No. 10/582,223, which published as US 2007-0081950 A1, and which has previously been cited in Applicant's Information Disclosure Statement and Supplemental Information Disclosure Statement, and in the priority information in Applicant's response filed March 4, 2010. Moreover, as previously advised in the priority information in Applicant's response filed March 4, 2010, Application No. 10/582,223 is the national stage of PCT/EP03/13873 of which the present application is a continuation-in-part. The Examiner was requested to review the file wrapper of this parent application at the Patent and Trademark Office, including the Office Actions mailed therein. Accordingly, the Examiner should be considering the parent application and its national stage application when reviewing

the present application. However, to ensure that the record reflects such consideration, Applicant is presently listing information cited in the parent application but not formally of record in the present application on a Form PTO-1449. Accordingly, a fee and/or certification should not be necessary for consideration of the information cited in the Third Supplemental Information Disclosure Statement. However, authorization is hereby provided to charge any necessary fee to Deposit Account No. 19-0089.

**Priority**

Applicant once again acknowledges the Examiner's indication regarding the parent PCT application, and reminds the Examiner that PCT/EP03/13873 entered the U.S. national stage and was awarded Application No. 10/582,223, and published as US 2007/0081950 A1. The Examiner is once again requested to review the file wrapper of this parent application at the Patent and Trademark Office, including the Office Actions mailed therein. If the Examiner needs any documents, the Examiner is requested to contact the undersigned.

**Restriction Requirement**

Applicant is permitting non-elected claims 16-21 to remain pending subject to rejoinder upon allowance of the elected subject matter.

**Response To Art Based Rejections**

The following art based rejections are set forth in the Office Action:

(a) Claims 1-4, 6-9, 11-13 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/19668 to Tame-Said in view of U.S. Patent No. 3,928618 to Bauman.

(b) Claims 11, 14, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/19668 to Tame-Said in view of U.S. Patent No. 3,928,618 to Bauman, and further in view of U.S. Patent No. 6,682,722 to Majeti et al. (hereinafter "Majeti").

(c) Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/19668 to Tame-Said in view of U.S. Patent No. 3,928,618 to Bauman, and further in view of U.S. Patent No. 6,685, 912 to Holme et al. (hereinafter "Holmes").

Initially, Applicant notes that paragraph (7) of the Final Office Action is apparently inadvertently included therein as the rejection set forth in this paragraph is stated to have been withdrawn in paragraph (4) of the Final Office Action. Accordingly, this withdrawn ground of rejection is not being addressed in the present response as having been withdrawn.

Moreover, in response to these grounds of rejection, Applicant submits that Tame-Said in view of Bauman does not teach or suggest the subject matter recited in Applicant's claims for at least the reasons set forth herein, and none of the documents used in the rejections of record, whether taken alone or in any combination, overcomes the deficiencies of any combination of Tame-Said and Bauman.

Tame-Said discloses a toothpaste and mouthwash composition in tablet form which dissolves in the mouth. The express object of the composition of Tame-Said as stated in the Abstract of Tame-Said is the prevention of periodontal diseases. By contrast, Applicant's claim 1 is directed to a tooth whitening lozenge composition comprising a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

- a) a water-soluble lozenge base,
- b) lozenge additives, and

c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

Furthermore, Tame-Said teaches that each tablet comprises ascorbic acid, sodium bicarbonate tricalcium phosphate, sodium lauryl sulfate, arabic gum, natural sweeteners and flavouring agents. However, Tame-Said appears to be silent on the use of calcium pyrophosphate in the composition. In addition, Tame-Said appears to be silent relating to tooth whitening.

The fact that tricalcium phosphate is a polishing agent as allegedly evidenced by Bauman is immaterial to the question of whether a skilled artisan would have desired any tooth whitening effect in the composition disclosed in Tame-Said. There is no teaching or suggestion of any desirability of tooth whitening in the composition of Tame-Said.

Bauman relates to oral compositions consisting essentially of a non-ionic organic surfactant and a quaternary ammonium aryl ester (Bauman, column 1, lines 7-10). The quaternary ammonium aryl ester is found to possess bacteriostatic effectiveness (Bauman, column 2, lines 3-36). The composition of Bauman thus exhibits anti-microbial, anti-caries and anti-calculus properties, as disclosed in the abstract of Bauman. Hence, Bauman also relates to an objective that is different from the tooth whitening of Applicant's claimed subject matter.

In addition, Bauman teaches, beginning at column 4, line 66, that the oral composition may be incorporated in a dentifrice, such as a dental cream, tablet or powder. As a vehicle, the dentifrice may contain 20-95% of a water-insoluble polishing material selected from a variety of possibilities including calcium pyrophosphate (Bauman, column 5, lines 3-4). The only example in Bauman containing water-insoluble phosphates relates to a dental cream (Bauman, Example 1, at column 6) containing 46.75% dicalcium phosphate dihydrate. Clearly and as acknowledged by

Bauman, the application of dental cream typically involves the mechanical application by brushing the teeth thereby achieving abrasive effects (Bauman, column 6, lines 3-6).

Significantly, the remaining examples in Bauman relate to mouthwash not containing any polishing agent whatsoever (Bauman, column 6). In contrast to dental cream, mouthwash is not applied by mechanical brushing action.

Thus, one having ordinary skill in the art would not have combined the disclosures of Tame-Said and Bauman in the manner asserted in the rejection, especially when Tame-Said is directed to a toothpaste and mouthwash composition in tablet form which dissolves in the mouth, and Bauman does not disclose a polishing agent in his mouthwash examples.

According to the present invention, calcium pyrophosphate has been surprisingly found to exhibit improved stain removal when incorporated into a lozenge comprising a water-soluble lozenge base. Applicant's composition provides a composition that through a water-soluble lozenge achieves tooth-whitening effectiveness of calcium pyrophosphate without needing mechanical application. It is surprising that such tooth-whitening effectiveness is not limited to mechanically applied (e.g., by brushing action) oral compositions such as dental creams, but is seen to a surprisingly high degree in a lozenge composition that merely dissolves in the oral cavity owing to the water-soluble lozenge base.

At best, one having ordinary skill in the art learns from Bauman that calcium pyrophosphate may be used as one of many possible polishing materials in dental cream. However, Bauman is silent on tooth whitening effects conferred on a lozenge or tablet composition, which is not applied mechanically, such effect being conferred by polishing materials in general and by calcium pyrophosphate in particular. To the contrary, one having ordinary skill in the art would understand from Bauman, in particular, from the examples therein,

that in oral compositions not requiring mechanical brushing application the use of polishing agents can be dispensed with since no tooth whitening effect is expected in this regard. Bauman thus clearly teaches away from such a modification.

Thus, for at least this reason, one having ordinary skill in the art would not have been motivated to substitute calcium pyrophosphate for tricalcium phosphate in a tablet composition according to Tame-Said. One having ordinary skill in the art would not seek to improve the improve tooth-whitening properties of Tame-Said's tablet composition, especially when Tame-Said appears to be silent in this regard, and would therefore not find any guidance in Bauman. Moreover, the disclosure of Bauman would lead to the conclusion that polishing agents, such as calcium pyrophosphate, are to be dispensed with in oral compositions that are not applied mechanically.

Moreover, the subject-matter of currently amended claim 1 is further defined over the cited prior art by the weight percentage of calcium pyrophosphate being 0.1 to 10% by weight of the composition. As acknowledged by the Examiner, Tame-Said teaches a weight percentage of 11.59% of tricalcium phosphate in the abstract. As explained above, Applicant submits that a person having ordinary skill in the art would not have modified Tame-Said by substituting calcium pyrophosphate for tricalcium phosphate based on the teaching of Bauman. However, even if for the sake of argument the disclosures were combined, one having ordinary skill in the art would not have arrived at the claimed range of 0.1 to 10% by weight.

The rejection has dismissed this range as an obvious result of routine experimentation quoting *In re Aller* (MPEP 2144.05). However, the rejection has not established that such parameter is obtainable by routine experimentation. First, Bauman points to a different direction, i.e., towards considerably higher weight percentages (20-95% column 4, line 66 to column 5,

line 5; 46.75%, column 6, Example 1). Moreover, MPEP 2144.05 IIB states that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" quoting *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the present situation, neither Tame-Said nor Bauman teach that the use of calcium pyrophosphate would achieve a tooth whitening effect in an oral composition that is not applied mechanically such as a lozenge. In fact, neither Tame-Said nor Bauman discloses that the weight percentage of calcium pyrophosphate would be of any relevance in this regard.

Still further, Bauman does not disclose polishing agents such as calcium pyrophosphate in oral compositions that are not applied mechanically (Examples 2 and 3 as contrasted to Example 1). Thus, the weight percentage of calcium pyrophosphate in a lozenge composition can hardly be considered a result-effective variable based upon the teachings of Tame-Said and Bauman.

Applicants therefore respectfully submit that the claimed range is not obtainable by routine experimentation following the disclosures of Tame-Said and/or Bauman.

Still further, Applicant submits that any combination of the cited documents would not arrive at the subject matter recited in Applicant's dependent claims at least for the reasons set forth above, and for the additional features recited in dependent claims in combination with the subject matter from their parent claims.

For at least the reasons set forth above, the rejections of record should be withdrawn with the early mailing of the Notices of Allowance and Allowability.

**CONCLUSION**

Entry and consideration of the present amendment, reconsideration of the Final Office Action, and allowance of the present application and all of the claims therein are respectfully requested and believed to be appropriate.

Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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